

# TAB G



United States  
**CONSUMER PRODUCT SAFETY COMMISSION**  
Washington, D.C. 20207

**MEMORANDUM**

DATE: July 21, 1997

TO : Scott Heh, Project Manager, ESME  
Through: Robert B. Ochsman, Division Director ESHF  
FROM : Celestine Trainor, ESHF

A handwritten signature, likely of Robert B. Ochsman, is written over the "Through:" line.

A handwritten signature, likely of Celestine Trainor, is written over the "FROM:" line.

SUBJECT: Human Factors' Response to Comments on Federal Register  
Notice for Bicycle Helmet Regulations

The Consumer Product Safety Commission published the proposed safety standard for bicycle helmets in the Federal Register on December 6, 1995. Below is Human Factors' response to the public comments in response to the proposed rule. The numbers in parenthesis refer to the comment number assigned by the Office of the Secretary to the respondent.

Issue: 1203.18 - Reflectivity (CC96-1-1, 7, 11, 13, 16, 17, 22, 23, 24, 26)

Several respondents urged that the Commission not postpone implementing reflectivity requirements while it conducts further study.

Response: As discussed by Human Factors in a memorandum dated Aug 28, 1995, reflectivity is an important issue and is being considered. However, it is staff's opinion that more research is necessary to adequately establish the minimum level of reflectivity that should be considered as a requirement in the CPSC bike helmet standard.

The Commission conducted field testing on bicycle reflectors and examined the issue of reflectivity on bicycle helmets. In the field testing, half (24/48) of the subjects saw bicycle riders with reflective helmets and the other half saw non-reflective helmets. The reflective tape used on the helmets met a proposed standard on use of retroreflective materials on bicycle helmets that was balloted by the ASTM Headgear Subcommittee. Study results failed to show that the particular helmet reflective strip used in the study would increase the distance at which a bicycle can be detected or recognized (Schroeder, 1997). For that reason, Human Factors still believes more research should be conducted to determine minimum retroreflective requirements.

Issue: 1203.6(a) (5) - Labeling of cleaning products  
(CC96-1-2, 11, 12, 29)

Several respondents expressed concern that too much information about cleaning products would be needed on the label and argued that consumers should be directed to the instructions manual for the list of cleaning materials.

Response: This requirement is to advise consumers that some cleaning products can damage the helmet and to provide some guidance as to what cleaning products should and should not be used. This label is not intended to list every possible cleaning agent that should or should not be used on the helmet. Cleaning is a common procedure and,, therefore, consumers are not likely to look for directions for cleaning. The reason for the label is to have pertinent information readily available to the consumer at the time of cleaning. Simply stating that some products could damage the helmet and directed to check the manual for specifics may seem reasonable, but if the consumer does not have the manual they have no guidance as to what should and should not be used. Providing them with information about some, not all, common cleaning agents (in generic terms) allows them to make a decision about what may be appropriate. 'For example, if bleach or abrasive soaps can damage the helmet, the label should state that, as opposed to listing specific brands of items. Generic terms should also be used for recommended cleaning items, for example, clean with mild soap and a damp cloth. Then the label can direct consumers to the instruction manual for more specific information on care and cleaning procedures.

Human Factors recommends clarifying this section with the following wording:

Sec 1203.6(a)(5) A warning to the user that the helmet can be damaged by contact with common substances (for example, certain solvents [ammonia], cleaners [bleach], etc.), and that this damage may not be visible to the user. This label shall state in generic terms some recommended cleaning agents and procedures (for example, wipe with mild soap and water), list the most common substances that damage the helmet, warn against contacting the helmet with these substances, and refer users to the instruction manual for more specific care and cleaning information.

Issue: 1203.34(c) Coding of Production Date (CC-96-1-11, 16,  
24, 26)

Several respondents were opposed to allowing manufacturers to code the month and year the product was manufactured. Their reasoning was that if there was a recall consumers would not be able to figure out if their helmet was part of the recall because the production date was coded. One respondent commented that if helmets should be replaced after five years, an uncoded production date is necessary.

Response: In the event of a recall, providing the manufacturing date in uncoded format would certainly make it easier for consumers to take the first step toward identifying their helmet. In addition, the Snell helmet standards require the use of uncoded production dates and it is common practice within the industry to use a conventional date format. Therefore, allowing coding would be counterproductive.

The issue of knowing when to replace the helmet is valid. However, the production date may not be an accurate reflection of the helmets "use" life. If the helmet was not in use for three of the five years since production, it may not be necessary to replace it. The uncoded production date would allow consumers who receive the helmet secondhand to know when it was produced, but it would not necessarily tell them when to replace it.

After considering the pro and cons for coding or not coding the production date, Human Factors judges it to be more beneficial to consumers to have the date uncoded. In the uncoded format, it is easier for consumers to identify their helmets. Once identified, they can take the appropriate action in the event of a recall.

Issue: 1203.34(d) Placement of the label(s) (CC96-22)

The respondent requested that the final standard require that the certification compliance label, which is required on the packaging if the label is not immediately visible on the product, be legible and prominent, and be placed on the main display panel of the packaging so that it is easily visible to the purchaser.

Response: The reason for requiring the label on the packaging, if it is not visible on the product at time of purchase, is to inform the consumer of compliance. Human Factors agrees with the respondent and suggests the following wording be added to section (d) :

1203.34(d) The label shall be legible, readily visible and placed on the main display panel of the packaging, or if packaging is not visible before purchase, on the promotional material used with the sale of the bicycle helmet.

Issue: 1203.6(a)(6) Label "For Bicycle Use Only" as opposed to "Not for Motor Vehicle Use" (CC96-1-11, 13, 22, 26)

Two respondents stated that "Not for Motor Vehicle Use" suggested the helmet was appropriate for other activities which may not be appropriate. Another respondent felt that "Not for Motor Vehicle Use" allows the helmet to be used for other activities similar to bicycle riding, where no alternative helmet exists. A third respondent argued that "For Bicycle Use Only" was a positive statement to which users are more likely to respond.

**Response:** After further review of the comments for and against "Not for Motor Vehicle Use" and "For Bicycle Use Only", Human Factors judges that neither label adequately conveys the "use" circumstances under which helmets that meet this regulation are appropriate. The certification label, on the other hand, states that the helmet is certified to meet CPSC requirements for bicycle helmets. The certification label will assure consumers that the helmet provides head protection while bicycling. Other wheeled recreational activities, such as traditional rollerskating and in-line skating, are typically conducted on the same surfaces as bicycling and can generate speeds similar to bicycling. Therefore, it is reasonable to assume that helmets that meet the requirements in the CPSC bike helmet standard will also provide head protection for roller/in-line skating and perhaps some other recreational activities. If someone wants to wear a CPSC-certified bike helmet for in-line skating, he or she should not be discouraged from doing so by a label that states "For Bicycle Use Only."

Staff is not aware of any information that concludes that bicycle helmets are widely misused in motor vehicle activities. Human Factors believes that consumers understand both the differences between bicycle helmets and motorcycle/motorsport helmets and that bicycle helmets would not provide adequate protection for motorsport activities. Therefore, Human Factors believes that a "Not for Motor Vehicle Use" label is not a critical safety message that should be mandated in the CPSC standard. However, the CPSC standard should not prevent manufacturers from having additional labels or warnings on the appropriate or inappropriate "use" of their helmets. As part of their internal policy, manufacturers may decide to place on their helmets a "Not for Motor Vehicle Use" label or a "For Bicycle Use Only" label and the standard should not prevent them from doing so.

Based on the discussion above, Human Factors recommends that the CPSC standard not require a "use" label, but maintain the requirement for a certification label that informs the consumer that the helmet is certified as suitable head protection for bicycling.

**Issue:** 1203.4(b) Definition of helmet (CC96-1-12)

The respondent disagreed with the inclusion of headgear which "...has a reasonably foreseeable use as, a device intended to provide protection from head injuries while riding a bicycle."

**Response:** For the same reasons that it is reasonable to assume that consumers will use bicycle helmets for other non-motorized sports such as roller skating, in-line skating and skateboarding, helmets for these sports could foreseeably be used while bicycle riding. Therefore, these helmets, if marketed or implied through promotional materials to be appropriate for bicycle riding, should meet the bicycle helmet standard.

The respondent suggested that "football helmets, baseball batting helmets, and motorcycle helmets" will also be "easily foreseeable" uses as bicycle helmets; Human Factors staff disagrees. The design of these helmets and the activities for which they are intended (except motorcycle riding) are not similar to and are not typically associated with bicycle riding. Therefore, the helmets for these activities are not likely to be used as bicycle helmets. As for motorcycle helmets, the size and construction of these helmets will likely deter bicyclists from using them while bike riding. In fact, one of the most frequently reported reasons stated for not wearing a bicycle helmet is because they are too hot; another is that they are too bulky. Current bicycle helmets are smaller, and lighter than motorcycle helmets, so it is unlikely consumers will use the larger motorcycle helmet for bicycle riding.

Human Factors judges that the helmets mentioned by the respondent would not likely be considered "reasonably foreseeable use..." as stated in the proposed definition of bicycle helmet. However, in order to provide more guidance through the definition, Human Factors recommends the definition read:

*Bicycle helmet* means any headgear that either is specifically marketed as, or implies through marketing and/or promotional information to be, a device intended to provide protection from head injuries while riding a bicycle.

**Issue:** 1203.6(a)(3) & 1203.6(b) Fitting Label & Instructions  
(CC96-1-11, 22)

One respondent stated that helmets designed and intended for children be accompanied by fitting instructions which are crafted in age-specific language. Both respondents stated their belief that "proper fit" information should be on both the helmet and the outside of the box.

**Response:** Human Factors judges an age-specific instruction sheet unnecessary. The proposed standard currently requires graphics, along with written fitting directions, on the instruction sheet. The graphics are better able to reach more children than age-specific instructions because they allow children of all ages to compare the way their helmet looks with the pictures. In addition, graphics are able to convey the critical information to non-English reading individuals and illiterates. Children and adults are likely to be better able to understand and appreciate the pictures. The written instructions can then be used by parents/guardians as read--along material. The adult and child can discuss the instructions as they relate to the pictures. This is more likely to effectively deliver the message, allowing both parents and children to become aware of the proper fit.

A label on the box promoting the need for "proper fit" could inform parents, before they buy the helmet, that they need to properly fit the helmet to the child. Staff does not believe it is necessary to have the actual fitting instructions on the box, because staff is not aware of any information which indicates that such a label would be effective in assuring proper fit. However, it is important that consumers be aware that helmets do come in different sizes and that proper fit is important. Therefore, HF recommends that section 1203.6 (a)(3) also apply to the helmet packaging.

**Issue:** Conspicuity of 5 years replacement requirement for users having little command of the English language (CC96-1-11)

The respondent requested: "... that the section of the label which addresses the five (5) years of age replacement requirement be very conspicuous and easily understood. Making this portion of the label conspicuous and easily understood will benefit helmet users having little command of the English language."

**Response:** The proposed standard does not have a "five year replacement requirement." The determination of the intended life of the helmet is the manufacturer's responsibility. Regardless, Human Factors judges that all labeling currently proposed for inclusion on the helmet is important for the user. For that reason, all such labels are required to be legible and easily visible to the user.

In addition, the life of a helmet is dependent on its use. Helmets that are used frequently and subjected to weather and poor handling may have a shorter life time than helmets that are only used once or twice a year. It is staff opinion that the decision to have a label stating the recommended replacement period be left to the manufacturer.

**Issue:** Minimum Age for Special Coverage (CC96-1-21)

This respondent (the American Academy of Pediatrics) agreed with the Commission's proposal for separate helmets for young toddlers, but requested that a minimum age of 1 year be required. The respondent stated that infants under 1 year should not be passengers on bicycles and therefore, helmet labeling should not mislead consumers into thinking it is acceptable for them to ride on bikes as long as they have a helmet.

**Response:** Staff agrees with the American Academy of Pediatrics that children under one year of age should not be on bicycles. Developmentally, children are just learning to sit unsupported around 9 months of age. It is not until this age that infants have developed sufficient bone mass and muscle tone to enable them to sit unsupported with their backs straight. Pediatricians advise against having infants sitting in a slumped or curled position for prolonged periods. This possibility may even be

exacerbated by the added weight of a bicycle helmet on the infant's head. Staff believe that helmets labeled for use by children under one may mislead consumers to believe that children under one year can be bicycle passengers.

Human Factors staff recommends labeling helmets for children under 5 years with a minimum age of 1 year.

Issue: 1203.34(b)(1) Contents of Certification label  
(Toddler/Children's Helmet -- 5 years of age)  
(CC-96-1-12, 13, 27)

The proposed wording for certification is "Complies with CPSC Safety Standard for Bicycle Helmets for Adults and Children Age 5 and older (16 CFR 1203)," "Complies with CPSC Safety Standard for Bicycle Helmets for Children under 5 Years (16 CFR 1203)," or "Complies with CPSC Safety Standard for Bicycle Helmets for Persons of All Ages." Some respondents expressed concern that parents will need to buy a new helmet on their child's fifth birthday. Respondents stated that head size should be the determining factor for change, not age.

Response: One of the first things conveyed to parents about children is that they will develop at different rates and developmental information that indicates a specific age should be used as a guideline. Therefore, it is likely parents will take the labeling on the bicycle helmet in the same vein. While using head size is an objective measurement for laboratories to use, this is not information commonly available to consumers, particularly about children. Typically, clothing sizes are associated with children's ages. Parents know the ages of their children and look for clothing for that age group as a starting point. The same is likely to be true for bicycle helmets. Parents are more likely to use the guidelines of 5 years as a point to evaluate whether the helmet currently used by the child still fits properly, or if it is time to move on to the next size/style helmet.

In the proposed regulation, helmets for children under 5 years cover a larger area of the head and have an acceptable peak acceleration of impact force 50 g less than the older child/adult helmets. Since the extra coverage is a benefit to children 5 years and older as well as under 5 years, it would be appropriate to label the helmet to reflect this. Human Factors recommends changing the conformance statement to read:

**"Meets** CPSC Safety Standard for Bicycle Helmets for Children 1 to 5 years (Extended Head Coverage)"

Human Factors' staff disagrees with one respondent's comment "...that parents may give up and not comply with any of the helmet messages because they have become too **confused**" by the differences between toddler (1 to 5 years) and children's (5 years and older) helmets.. The fact that a parent has taken the



time to get a helmet, or even look into the issue of getting a helmet,. suggests that they have received some information that compelled them to consider the safety benefits a helmet offers to their child. In addition, more and more states are mandating helmet use for children, thus requiring parents to get helmets for their children. They will use the age guidelines and the proper fit instructions to determine the appropriate helmet for their child.

Issue: 1203.34(b) (1) and (d) - Certification Labeling on Helmet and Packaging (CC96-1-29)

The respondent agrees that distinguishing stickers for helmets for toddlers/children vs. youths/adults should be placed on the packaging because it is relevant to the consumer at the time of purchase, but contends it is not necessary on the helmet.

Response: Human Factors staff disagrees with the respondent's statement that the information is only necessary on the box, especially when dealing with children's helmets. Toddler (1 to 5 years) helmets are likely to be passed/shared with multiple users, and, therefore, the sticker on the helmet is likely to be the only source of information available to the second or third user. Also, smaller sized youth/adult helmets may be mistaken as being appropriate as toddler helmets just because of the size. The sticker inside, again, may be the only source of information to the user. Further, it is common to display helmets at retail without the box. Thus, the purchaser may not see the box until after selecting the model, if at all. Therefore, Human Factors recommends leaving this labeling both on the box and inside the helmet.

Issue: 1203.34(b) (1) and (d) - Certification Labeling on Helmet and Packaging ((X96-1-22)

This respondent encourages the Commission to modify the certification labeling to require the language "United States Consumer Product Safety Commission" rather than "CPSC". The respondent believes the acronym is likely to lead to consumer confusion, but the use of the formal name of the Commission will clearly identify the helmet as meeting a federally established safety standard.

Response: The rationale presented by the respondent for using the full name of the Commission instead of using the acronym is logical. However, the use of the Commission's full name may be impractical for some manufacturers. The amount of space available on the inside of a helmet is limited. The proposed regulation requires a number of labels and each one is supposed to be legible and easily visible to the user. Allowing the use of the acronym is a necessary compromise so that all the labels can be accommodated on the inside of the helmet. However, staff

believe it should be the manufacturers choice and the following wording should be added to section 1203.34(b)(1):

"Manufacturers can use the CPSC abbreviation or spell out U.S. Consumer Product Safety Commission on this label."

**Issue:** 1203.6(a) (4) - Warning to replace after impact  
(CC-22, 23, 26)

Some respondents agreed with the staff's position that the label on the helmet should advise consumers to return the helmet to the manufacturer or destroy it if it is involved in an impact. Others disagreed and requested more guidance on whether the helmet is impaired before a consumer has to go through the hassle of returning the helmet.

**Response:** The variety of factors (i.e., impact surface, impact location on helmet, speed and distance of impact, etc.) that are involved in an impact to a helmet, and the level of interaction of each factor, are so complex, it is inappropriate to address them in a label. It is to the consumer's overall safety benefit to return the helmet to the manufacturer or destroy and replace it.

Human Factors recommends leaving the replacement warning as currently proposed.

**Issue:** 1203.6(a) (2) - Warning against injury (CC-22, 23)

These respondents urged the Commission to require "an appropriate symbol to appear adjacent to the statement of compliance on the label" and to add wording to warn that "failure to follow the warnings may result in serious injury or death (because the helmet could not perform in the manner intended)."

**Response:** The Commissions staff has certainly been and continues to be an advocate for the use of the ANSI labeling format. However, use of this labeling standard for bicycle helmets would be burdensome. The limited size of the inside of a helmet and the amount of information proposed for placement on labels inside the helmet restricts the use of the full ANSI labeling recommendations. The respondent's recommendation to have an "appropriate symbol to appear adjacent to the statement of the compliance on the label" would certainly enhance the label. In this case, however, the use of the safety word "WARNING" is more appropriate than just a symbol. Many manufacturers currently abide by this practice, and, therefore, it would not put an additional labeling burden on them to specifically require the use of this safety word.

In addition, most manufacturers already warn that helmets are not able to prevent all types of injuries and that serious injury or death could occur. The respondent urges the Commission to associate this message with failure to follow all warnings.

In actuality, serious injury or death can occur even if the helmet is fitted properly, therefore, staff believes the message should be included with the message that no helmet can protect against all possible impacts. Section 1203.6(a)(3) already stresses the issue of fit.

For the reasons given above, Human Factors staff recommends the following changes to section 1203.6:

(a) (2) A warning to the user that no helmet can protect against all possible impacts and *that* serious injury or death could occur.

(b) ~~Instructions.~~ Signal word. Sections (2)-(5) shall include the signal word "WARNING" at the beginning of each statement; if two or more of the statements appear on the same label, the signal word need only appear once at the beginning.

(b) (1) The signal word "WARNING" shall be in all capital letters, bold print, and a type size equal to or greater than the other text on the label.

(c) Instructions.

# TAB H



United States  
**CONSUMER PRODUCT SAFETY COMMISSION**  
Washington, D.C. 20207

**MEMORANDUM**

**DATE:** OCT 16 1996

**TO :** Celestine Trainor, ESHF

**Through:** Mary Ann Danello, Ph.D., Associate Executive Director  
Directorate for Epidemiology and Health Sciences *mad*  
Robert E. Frye, Director *B*  
Hazard Analysis Division (EHHA)

**FROM :** Terry L. Kissinger, Ph.D., EHHA *TLK*

**SUBJECT:** Experimental Design for Bicycle Reflector Study

This memorandum provides a description of the experimental design of the proposed bicycle reflector study. The methodology and objectives of the study are discussed; the layout for the experimental design is given; and procedures for analysis after the study is conducted are indicated.

**I. Methodology and Objectives of the Study**

In this study, test subjects driving a motor vehicle under standardized conditions will encounter six bicycle riders with different levels of reflectivity and six stationary decoys. The bicycle riders and decoys will be placed at 12 different locations and encountered sequentially by each driver. The placement of the six bicycle riders at six locations will not be the same for all test subjects. The motor vehicle will be equipped with a recording device, which the experimenter will control to measure subject detection of each of the 12 objects and subject recognition of each of the 12 objects.

The dependent-variables are the distance at which the driver detects an object and the distance at which the driver recognizes an object, both continuous. The independent variables are target (six levels, corresponding to the six bicycle riders with different levels of **reflectivity**); location (six levels, corresponding to the six locations at which a bicycle rider can be placed); night-of testing (with as many levels as nights used for testing); test subject (with as many levels as test subjects chosen for the study); helmet reflectivity (two levels, corresponding to whether the bicycle rider's helmet has a

reflective band); and age group (two levels, corresponding to the two defined age groups from which subjects will be chosen for testing).

The objective of the study is to evaluate the conspicuity of nighttime bicycle riders to motor vehicle drivers. Thus, interest is in contrasts of the mean distance of detection and the mean distance of recognition of the six levels of target, controlling for variability due to location, night of testing, test subject, helmet reflectivity, and age group. This will be a repeated measures study, and because the number of levels of target equals the number of levels of location, a square design would seem appropriate.

## II. Experimental Design

It is recommended that a cross-over design (which involves a multiple number of latin squares) be employed for this study. Cross-over designs are useful when a latin square is to be used in a repeated measures study, yet more subjects are required than called for by a single latin square.<sup>1</sup>

The following 6 X 6 square may be found in Cox (1958)<sup>2</sup>:

A	B	F	C	E	D
B	C	A	D	F	E
C	D	B	E	A	F
D	E	C	F	B	A
E	F	D	A	C	B
F	A	E	B	D	C

For this study, the rows pertain to six test subjects, the columns pertain to the six possible locations for the six targets, and the letters pertain to the six targets. Thus, for each combination of an age group and a helmet reflectivity condition, a block of six test subjects would be tested in this manner, with the targets placed in the proper locations. It is recommended that two squares be used for each of the four possible combinations of an age group and a helmet reflectivity condition. This yields eight nights of testing (one night for each square) and a total of 48 test subjects.

It should be noted that this is a special type of latin square. It is arranged so that each treatment follows each other treatment exactly once. Squares such as this are often used in cross-over designs to allow for "carry-over" effects, in which the immediately preceding treatment has a "residual" effect.

## XII. Analysis

In this design, all **factors** are considered fixed." Night of testing is nested within age group and helmet reflectivity, and test subject is nested within night, age group, and helmet reflectivity. Thus, an analysis of variance table would have the following features:

Source of Variation	Degrees of Freedom
Target	5
Location	5
Age Group	1
Helmet Reflectivity	1
Age Group*Helmet Reflectivity (Interaction)	1
Night (Nested within Age Group and Helmet Reflectivity)	4
Test Subject (Nested within Night, Age Group, and Helmet Reflectivity)	40
Error	230
Total	287

An analysis would be conducted separately for each of the two dependent variables. Tests could be performed for the effects of each factor. Tests could also be performed for contrasts of means, particularly for target, the factor of main interest.

Note that it is assumed that there is no interaction of the various factors, except for age group and helmet reflectivity. Alternately, age group and helmet reflectivity could be considered as one factor with four levels instead of two factors with two levels each. Then, perhaps more simply, night would be nested within this four-level factor, and test subject nested within night and the four-level factor.

The data should be examined to see if the assumption of no interaction beyond that of age group and helmet reflectivity is valid. If it is believed that other interactions are present, an appropriate transformation of the data may eliminate the interaction effects.

### Endnotes

<sup>1</sup>See, e.g., *Applied Linear Statistical Models*, by John Neter and William Wasserman, 1974, p. 790.

<sup>2</sup>The square is presented and discussed on p. 273 of *Planning of Experiments*, by D.R. Cox, 1958. The use of cross-over designs in general is discussed in Chapter 13 of the book.

<sup>3</sup>As cautioned on p. 617 of *Applied Linear Statistical Models* by John Neter And William Wasserman, a random effects model should be used only if the levels of the different factors do indeed represent random samples from the population of interest.



# TAB I



**U.S. Consumer Product Safety Commission**  
**Washington, D.C. 20207**

**Memorandum**

October 5, 1997

**To** : Celestine Trainor, ESHF

**Through** : Mary Ann Danello, Ph.D, Associate Executive Director *MD*  
Directorate for Epidemiology and Health Sciences -----  
Susan Ahmed, Ph.D, Director *SA*  
Hazard Analysis Division (EHHA)

**From** : Tom Schroeder, EHDS *T.S.*

**Subject** : The Bicycle Reflector Study Data: The Effect Of Helmet Reflectivity

This memorandum provides an analysis of data from the bicycle reflector study to determine the effect of helmet reflectivity. The analysis is given in two separate sections; one section for the distance at which a driver detects an object ahead, and another section for the distance at which a driver recognizes the object as a bicycle.

**Background**

In this study, test subjects driving a motor vehicle under standardized conditions encountered six bicycle riders with different levels of reflectivity. The bicycle riders were placed at six different locations and encountered sequentially by each driver (See appendix for a brief description of the six levels of reflectivity and the physical description of the six different locations). The placement of the six bicycles for each driver followed a cross-over design of a multiple number of latin squares.<sup>1</sup> The motor vehicle the test subject drove was equipped with a recording device, which an experimenter controlled to measure the subject detection of each of the six bicycles and the subject recognition of the bicycles.

There were a total of 48 subjects tested over a period of 8 nights in this experiment. Note that 3 of the subjects were not tested on the night designated by the experimental design. This further complicated the analysis. Half of the subjects were between age 25 to 34 and half of the subjects were between age 35 and 44. The subjects were evenly split by gender. There were also two different levels of helmet reflectivity involved corresponding to whether the bicycle rider's helmet had a reflective band.

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<sup>1</sup>See Kissinger, Terry L. "Experimental Design For Bicycle Reflector Study", Oct. 16, 1996.

Based on the experimental design, an analysis of variance table had the following features:

**Table 1: Analysis Of Variance Table**

Source Of Variation	Degrees Of Freedom
Target	5
Location	5
Age Group	1
Helmet Reflectivity	1
Age Group*Helmet Reflectivity (Interaction)	1
Night (Nested within Age Group and Helmet Reflectivity)	4
Test Subject (Nested within Night, Age Group, and Helmet Reflectivity)	40
Error	230
Total	287

### Detection Distance Of The Bicycles

The experiment was designed based on the assumption that there would be no interaction of the various factors except for possibly age group and helmet reflectivity. The data was analyzed and it was confirmed that no other interaction existed. The factors found to be significant at a 95% confidence level for the distance at which the bicycles were detected were **target**, **location**, and **subject**. Note that because night was not found to be a significant factor, the three subjects tested on the non-designated nights did not adversely affect this part of the analysis.

The detection distance followed the following model:

$$\text{Detection Distance} = \beta_0 + \beta_1 \text{target} + \beta_2 \text{location} + \beta_3 \text{subject}$$

Of primary interest in this memorandum is the effect of helmet reflectivity. As seen in the above model, helmet reflectivity was not a significant factor in this experiment. The data show that this particular helmet reflective strip did not increase the distance at which a bicycle was detected.

The mean detection distance by helmet reflectivity is listed in table 2.

**Table 2: Mean Detection Distance By Helmet**

Target	Mean Detection Distance (In Feet)	Standard Deviation (In Feet)
Non-reflective Helmet	777	21
Reflective Helmet	748	21

### Recognition Distance Of The Bicycles

As in the detection distance of the bicycles, the experiment was designed based on the assumption that there would be no interaction of the various factors except for possibly age group and helmet reflectivity. The data was analyzed and it was confirmed that no other interaction existed. The factors found to be significant at a 95% confidence level for the distance at which the bicycles were recognized were **location**, **night**, and **subject**. Note that because night was found to be a significant factor, the three subjects tested on non-designated nights complicated the analysis. There is also an indication that helmet might be a significant factor, but without further testing this cannot be verified.

The recognition distance followed the following model:

$$Recognition\ Distance = \beta_0 + \beta_1 location + \beta_2 night + \beta_3 subject$$

Several directions were taken in trying to determine the effect the 3 subjects tested on **non-designated** nights had on the overall analysis. The first direction that was taken was to throw out the data from these 3 subjects and treat them as missing values. When this was done, location, helmet, and subject were found to be significant factors. Night was no longer significant. This direction was not desirable though because the experiment was originally designed to get the maximum amount of information out of the minimal number of observations. By throwing out the data for the 3 subjects tested on the non-designated nights, there would be less than the minimal number of observations needed.

Another direction that was taken was to compute a regression equation using all the data and then try to predict what the recognition distances would have been for the 3 subjects if they had been tested on the night the experimental design called for. Again, location, helmet, and subject were found to be significant and not night. This direction is also not desirable because the regression equation was not that good of a fit to the data. This indicates that the predicted values for the 3 subjects could be greatly different than what the actual values would have been if the 3 subjects were tested on their designated nights. Further testing would have to be done to determine the true effect the 3 subjects tested on non-designated

nights had on the final model.

Of primary interest with the recognition distance is determining if the mean distance is significantly different by helmet. The analysis of the data does not indicate that the reflective strip on a helmet increases the distance at which a bicycle is recognized.

The mean recognition distance by helmet reflectivity is listed in table 3.

**Table 3: Mean Recognition Distance By Helmet**

<b>Target</b>	<b>Mean Recognition Distance (In Feet)</b>	<b>Standard Deviation (In Feet)</b>
Non-reflective Helmet	709	19
Reflective Helmet	674	21

There is no indication in the above analysis that the particular helmet reflective strip used in this study would increase the distance at which a bicycle can be detected or recognized. In fact for both detection and recognition distances in the above study, the mean distance was greater for the non-reflective helmet than the mean distance for the reflective helmet. However, the differences in the means were not statistically significant.

## Appendix

### Rear Approaching Target Description And Location Description

#### **I. Rear approaching target description**

Bike **1: Rear red blinking light**[1] with CPSC reflective lens, amber pedal reflectors, clear spoke reflector.

[1] Manufacturer - Cateye, model TL-LD500, 5 LED bulbs. 2AA batteries.

Bike **2: Florescent Yellow/Green reflective sheet material** covering large rear area below seat and pedal treatment, silver reflective tire rims.

Bike **3: Amber rear reflector**, ambler pedal reflectors and clear spoke reflectors.

Bike **4: White pedal reflectors**, red rear reflector, clear spoke reflectors.

Bike **5: Standard CPSC reflectors**,, red rear reflector, amber pedal reflectors, clear spoke reflectors.

Bike **6: Large red rear reflector**(German Z standard), amber pedal reflectors, clear spoke reflectors.

Bikes 1,3,4,6 were equipped with treatments similar to the standard bike 5 except for test treatment shown in bold text.

#### **II. Location Description**

Location 1: Street lighting with **dark** background.

Location 2: Street lighting with dark background and crossing traffic in the distance.

Location 3: Street lighting with building lighting in background.

Location 4: Dark, no street lighting, trees, on curve, dark background.

Location 5: Dark, no street lighting, on crest of a hill, dark background.

Location 6: Street lighting with building lights in background.

# TAB J



United States  
**CONSUMER PRODUCT SAFETY COMMISSION**  
Washington, D.C. 20207

**MEMORANDUM**

**DATE:** JUL 01 1997

**TO :** Scott Heh, Project Manager  
Division of Mechanical Engineering

**Through:** Robert G. Poth, *Director*  
Division of Regulatory Management

**FROM :** Francis J. Krivda, Compliance Officer *FK*  
Division of Regulatory Management

**SUBJECT:** Comments, on Proposed Bicycle Helmet Standard

**Location of certification testing records**

**Comment:** Test records should be made available to the Commission staff within 48 hours by all firms, not just the firms that keep their test records outside the United States under proposed rule, 1203.34(e) (1) (ii). This change will prevent United States firms from delaying providing the records to the staff. [Southwest Research Institute, CC96-1-2]

**Response:** The proposed rule requires that records may be kept by the importer outside the United States if the importer allows inspection by CPSC staff within 48 hours of a request by an employee of the Commission. This provision was added to provide flexibility to importers who want to maintain test records outside the United States and to insure that there would not be undue delays in providing testing records to the staff because the records were not physically located within the United States.

The staff has examined the comment and recommends that all firms be required to provide records for immediate inspection and copying upon request by a Commission employee. If the records are not physically available during the inspection because they are maintained at another location, we recommend that the firm must provide them to the staff within a maximum of 48 hours. Records that are not available during the inspection, whether maintained in the United States or outside the United States, may be transmitted quite rapidly by fax, express mail, or by electronic means. There are widely available methods available to provide records promptly that include not only express mail services but also communication hardware and software programs that can transmit records virtually instantaneously.



The Compliance staff recommends that this revision be made to the proposed rule in response to this comment and require all firms to provide certification records within 48 hours.

**Contents of certification label**  
**Coding date of manufacture vs using a common date format**

**Comments:** Under the proposed rule 1203.34(c), the coding of the date of production [1203.34(b)(6)] on the helmet by the manufacturer would prevent the second or third helmet users from knowing the age of the product. [American Society of Safety Engineers, CC96-1-11] Since manufacturers commonly recommend replacing a helmet after five years of use, the users could use the date of manufacture to assist them to remember the date of purchase and replace the helmets. Also, if a helmet is recalled, the user would likely remember the date of manufacture rather than the coded date. [Bicycle Helmet Safety Institute, CC96-1-16] Coding may make it easier to sell old helmets as new, make it difficult to know when to replace the helmets, to know when they were purchased, and to identify helmets if they are recalled. [Bicycle Federation of Wisconsin, CC96-1-24] If consumers have the date of manufacture prior to purchase, they could make better educated purchases. [Paula Romeo, CC96-1-26]

**Response:** The proposed rule 1203.34(c) permits the use of a code for the date of manufacturing rather than the uncoded date. The staff recommends the actual date of manufacturing be used instead of a coded date. This will make it easier for the consumers to know the actual date of manufacture of the product and facilitate product recalls and help consumers determine the age of the helmet for deciding when to replace it. Using the actual date will provide additional information to the users in the purchasing of bicycle helmets.

It is a common practice in the industry is to place the uncoded date of manufacture on the helmets. Therefore, it should not place an undue burden on the industry to use a standard date format on the helmets instead of a coded date.

The Compliance staff recommends a revision to the proposed rule under 1203.34(c) by requiring the manufacturing date to be in a common date format instead of the coded date in response to these comments.

**Adaption of Snell standards**

**Comment:** The Snell Memorial Foundation [CC96-1-28] and Paul H. Appel [CC96-1-25] propose the adoption of the pre-market clearance and the market surveillance provisions of the Snell standard to ensure that quality bicycle helmets are produced. According to the commenters, without these two Snell provisions,

government efforts will be insufficient in keeping inadequate helmets off the market.

**Response:** All firms must ensure that bicycle helmets sold in the United States are certified to the mandatory bicycle helmet standard, that the (certifications are based on reasonable testing programs, and that the helmets in fact comply with the standard. Firms that do not meet these requirements are subject to various Commission enforcement actions. These actions include recall, injunctions, seizure of the product, and civil and criminal penalties. The penalties for such violations could subject a firm to penalties of up to \$1.5 million and after notice of noncompliance, fines of up to \$50,000 or imprisonment of individuals for not more than one year, or both.

The Commission has statutory authority to conduct inspections of manufacturers, importers, distributors, and retailers of bicycle helmets. This authority includes the review and the copying of records relevant to determine compliance with the bicycle helmet standard. The Commission also has authority to collect samples of bicycle helmets for testing to the standard.

The Commission has a vigorous enforcement program that includes joint import surveillance with U.S. Customs and compliance surveillance of domestic producers, distributors, and retailers. In addition, the staff responds to all reports of noncompliance with all interim or final mandatory standards.

From previous history with other regulations that the Commission enforces, compliance with the various CPSC standards is high. In addition, all firms have a responsibility to report noncompliance with the standard under Section 15(b) of the Consumer Product Safety Act. Failure to report would subject a firm to severe penalties.

Based on these considerations, the compliance staff believes that the agency's enforcement programs and enforcement authority will provide substantial assurance that bicycle helmets will meet the requirements for the mandatory standard. Experience in enforcing other CPSC regulations has shown that a high degree of compliance can be achieved without manufacturers using a pre-market clearance program or a third-party certifying organization.

The Compliance staff recommends no revision to the proposed rule in response to this comment.

**Comment:** Norte Vista Medical Center [CC96-1-15] requested that helmets certified to the Snell B-95 or Snell N-94 Standards be considered to be in compliance with the regulation. The

commenter went on to state that the staff misunderstood its request regarding activities undertaken by Snell if defective helmets were encountered. Snell's position is that it would notify the Commission if there were a violation of the standard detected and had not planned to take action itself.

Response: One of the objectives of the Children's Bicycle Helmet Safety Act of 1994 is to establish a unified bicycle helmet safety standard that is recognized nationally by all manufacturers, importers, and consumers. Compliance staff believes it would defeat the intent of the Congressional act to add language to the regulation stating that certified conformance to any existing voluntary standard would satisfy compliance with the mandatory rule. This would complicate the marketplace for the consumers as there would be multiple standards that one can choose. In addition, having multiple standards would create a condition of unnecessary comparison between the standards, such as, which is the better standard.

The use of a third-party certification would also complicate the compliance process as reports of noncompliance with the third party certification process may not be failures of the proposed United States standard as the two standards would be somewhat different. Any noncompliance reported by a third party would have to be confirmed by the Consumer Product Safety Commission. Snell can report noncompliance with the proposed United States standard to the staff without the Commission requiring a separate third-party certification process.

The Compliance staff recommends no revision to the proposed rule in response to this comment.

#### OTHER COMMENTS

Comment: Trek USA [CC96-1-5] wants to change the wording of 1203.33(b)(4) from ". . . a bicycle helmet..." to "any bicycle helmet" that fails to meet the testing criteria. The commenter indicated that the wording of this section may result in the rejection of an entire lot if one helmet fails to meet the standard. The change would provide more flexibility as it would remove the possibility of an anomaly in the testing causing a rejection of an entire lot and the resulting lack of certification.

**Response:** The staff recommends no change in the wording in Section 1203.33(b)(4) from "a bicycle helmet" to "any bicycle helmet." First, it does not appear that the requested language would change the meaning of this requirement. Secondly, the testing requirement is flexible enough for each manufacturer/producer to ensure that their helmets meet the requirements of the standard.

The producer has the responsibility to set up a reasonable testing program tailored to meet his company's needs and to establish criteria to detect when helmets in a production lot fail to meet the standard. It is the responsibility of the bicycle helmet producer to ensure that the helmets certified do in fact meet the bicycle helmet standard. As long as there is a reasonable testing program in place, helmets that fail the standard will be detected. It is unlikely that a production lot will be rejected based on a failure of one helmet which might be an anomaly or an "outlier" when a firm has in place reasonable testing program. The purpose of the testing program is to detect possible failures of bicycle helmets in a production lot and to ensure that the helmets certified comply with the standard. The failure of one helmet would trigger an investigation to determine whether the failure would extend to other helmets in the production lot.

The Compliance staff recommends no revision to the proposed rule in response to this comment as each firm should have in place a testing program tailored to meet their needs.

**Comment:** The Protective Headgear Manufacturers' Association (PHMA) [CC96-1-29] wants clarification of the definition of "manufacturing lot." Both Troxel [C96-1-30] and PHMA want the latitude to establish accept/reject criteria for products that may contain variations or anomalies in production but meet the proposed standard.

**Response:** The proposed regulation is flexible to permit a firm to establish its own production lot along with acceptance and rejection criteria, as long as the process is reasonable. The manufacturing lot will probably vary as to the size of the firm. It would be difficult to mandate the size of a manufacturing lot and establish accept/reject criteria because each firm is different. It is the responsibility of each firm to establish a reasonable testing program to ensure that bicycle helmets in a production lot meet the standard. Once the mandatory standard is in place, it is critical that a firm has in place a quality control program that is tailored to its production lot. If not and the bicycle helmets fail to meet the mandatory standard they cannot be distributed as it would be a prohibited act under the Consumer Product Safety Act. If they were distributed and represent a hazard to consumers, the Commission has statutory authority to order a firm to repair or recall the helmets.

The Compliance staff recommends no revision to the proposed rule in response to these comments, as the proposed regulation provides the flexibility for each firm to set its own accept/reject criteria.

Comment: The Protective Headgear Manufacturers' Association (PHMA) [CC96-1-29] wants clarification of when there are material or vendor changes. PHMA requests that the staff use the "Definition of Term" drafted by Safety Equipment Institute (SEI) in 1994 to help firms understand the terms material changes, design changes, and vendor changes.

Response: The staff does not think that establishing definitions as stated in the SEI "Definition of Term" would add any significant clarification to the industry as a whole. Each firm has the responsibility to institute its own testing program, as long as the testing program is reasonable.

The intent of the regulation is to ensure that all firms establish a reasonable testing program and to provide flexibility for both large and small firms. Each firm has the flexibility to define their own terms in its quality control program, including material changes, design changes, and vendor changes, as long as the testing program is effective in ensuring that bicycle helmets comply with the standard.

The Compliance staff recommends no revision to the proposed rule in response to this comment.

Comment: Paula Romeo [CC96-1-26] commented that information on the helmet's certification label should not be coded because consumers should be able to read this information so they have an opportunity to make educated choices prior to purchasing a helmet. She stated that consumers should be able to read the name and address of the foreign manufacturer and the date of manufacture in order to make an educated purchase. She also indicated that testing should be done after a specified number of helmets are produced. In addition, certification records should be kept longer than three years as the Snell Memorial Foundation recommends helmets be replaced after five years. The manufacturer's telephone number should be required on the certification label since written correspondence to a responsible firm may take an unnecessary length of time.

Response: The use of codes on the bicycle helmet will not prevent a consumer from obtaining the name of the foreign manufacturer and the production lot information. The consumer may contact the firm who issued the certification as the name of the U.S. manufacturer/importer is required to be on the certification label. This information is required to be kept by each firm and the information must be provided to the consumer upon request under 16 CFR 1203.34(c)(ii). The staff agrees that the date of manufacture should not be coded and may help the consumer identify whether their helmet is subject to a recall as stated above. An uncoded date of manufacture is being used by

many bicycle helmet companies now and should not present a hardship to other firms.

It is the firm's responsibility to establish a reasonable testing program to ensure that the helmets it produces comply with the standard. It would not be necessary to require that testing be conducted on a specified number of helmets in a production lot. Each firm is different and is in the best position to establish its own production lot, sampling plan, and a reasonable testing program to ensure that the helmets it markets comply with the standards.

Most large companies already have consumer toll-free numbers affixed to the product to address consumers' concerns. During a recall or to inquire about a damaged bicycle helmet, the telephone number would be helpful for consumers to determine the status of their helmets quicker than a written inquiry. With a quicker response by having the telephone number, the consumer would reduce the chance of wearing a defective helmet by replacing it sooner with a safer helmet. The staff recommends that the telephone number be included on the labeling of the helmets.

The purpose for records to be kept for three years is to ensure that the helmets have time to clear the distribution channel and get into the marketplace. If there is a compliance problem or defect in the helmets, three years would be of sufficient time to uncover the problem. The Commission staff would have sufficient time to obtain the records to review the firm's testing program and take the necessary enforcement action during this three year period. The staff recommends no change in the record keeping retention time of three years.

The Compliance staff recommends the proposed rule be changed to include the uncoded the date of manufacture of the helmet and also for the importer or manufacturer to list the telephone number where consumers may obtain information about their helmets.

Comment: Consumer Federation of America [CC96-1-23] is concerned that the staff enforcement be vigorous for multi-use helmets marketed for bicycle use.

Response: Multi-use helmets marketed as suitable for bicycle use will be considered bicycle helmets under definition 1203.4(b) of the mandatory standard. These helmets must meet the mandatory standard and cannot be marketed unless they comply. The staff will enforce the provisions of the standard against these helmets if there is noncompliance with the standard. The staff has statutory authority under the Consumer Product Safety Act to bring action against the firm for failing to meet the standard.

**TAB K**



United States  
CONSUMER PRODUCT SAFETY COMMISSION  
Washington, D.C. 20207

MEMORANDUM

DATE: December 23, 1997

TO : Scott R. Heh, ESME  
Project Manager, Bicycle Helmets

Through: Warren J. Prunella, AED, EC *WJP*

FROM : Terrance R. Karels, EC *TRK*

SUBJECT: Bicycle Helmet Standard -- Small Business and  
Environmental Considerations

**Background**

In June 1994, Congress passed the Children's Bicycle Helmet Safety Act. The Act directed the CPSC to develop a mandatory standard for bicycle helmets, incorporating appropriate sections of the three voluntary standards extant for these products. In August 1994, the Commission published a Notice of Proposed Rulemaking (NPR) for bicycle helmets and solicited comments.

A July 1994 memo from Economics noted that any costs associated with design changes to comply with the proposed rule would be small on a per-unit basis. Costs associated with testing and monitoring were not expected to increase, since the vast majority of firms already used third parties to test for conformance to the voluntary standards. The proposal also allowed for self certification and monitoring which, for some companies, may be substantially less costly than third party certification. The memo noted that the proposed labeling requirements were unlikely to have a significant impact on small firms in that virtually all helmets already bore a similar label.

Based on this information, the Commission preliminarily concluded that the proposal would not have a significant impact on a substantial number of small entities. The Commission received no public comment on this conclusion. As a result of non-economic comments of a technical nature, the Commission proposed a revised standard on December 6, 1995. Economics staff reiterated its economic assessment of the economic impact of the standard on small businesses. In the preamble to the 1995 proposal, the Commission preliminarily certified that the proposed standard will not have a significant economic effect on a substantial number of small entities.



## Comments to the Proposal

The Commission received two comments on the 1995 proposal that related to the economic effects of the revision. These involved the cost associated with the specification of a monorail test device, and the effect of the curbstone testing procedure.

A comment from Trek Bicycle Corporation cited the need for a single test apparatus but was concerned that the Commission chose a monorail-guided test rig over wire-guided units. Trek said that some firms may be forced to purchase monorail units to eliminate product liability concerns, even though they already **have** wire-guided test units in place. The firm stated that "[T]he burden of this unnecessary expense may provide need for additional analysis of the financial impact to small business, as required by the Regulatory Flexibility Act."

Based on contacts with industry and testing facilities, Engineering Sciences staff report that of those manufacturers that have in-house test labs, an estimated five to ten have only **a** wire-guided rig. ES staff report that most commercial, independent, and academic bicycle helmet test labs have a monorail test rig, and many of those labs also have one or more wire-guided rigs. The estimated cost to acquire the monorail apparatus is about \$20,000 each.

An interlaboratory study comparing the results of monorail and guidewire rigs showed no significant differences between the two types of rigs in test conditions that are within the parameters of the draft final standard. Therefore, the staff has recommended that the final standard specify that either a monorail or a guidewire rig may be used to test for the impact requirements. Consequently, the potential cost considerations to laboratories using guidewire rigs should no longer apply.

Another commenter, Bell Sports, noted that the proposal also included impact testing requirements that allowed two impacts with a device simulating helmet contact with a curb. Bell estimated that "[T]he addition of the curbstone anvil . . . and the option of using it twice on any helmet might well increase the retail price of bicycle helmets by \$2.00 to \$10.00."

The proposed standard is intended to address helmet safety from a single impact on **a** given area. For this reason, the impact testing requirement has been changed to require only a single curbstone impact simulation test per helmet test sample. Consequently, the potential changes in helmet design that could have been needed to comply with **two** curbstone impact tests no longer apply.

## Small Business Effects

Of the 30 current manufacturers of bicycle helmets, all but two would be considered small businesses under Small Business Administration employment criteria (less than 100 employees). Economics staff stated in 1994 and 1995 memoranda that one-time costs of design are expected to be small on a per-unit basis. Information developed by staff during the comment period supports this statement.

Spokesmen for the Protective Headgear Manufacturers Association (PHMA) estimate that there are 1,000 to 1,500 molds in current use, each of which is composed of four cavities. Redesign may be required for one or more cavities in some molds, while other molds may not require any cavity redesign. Using a midpoint estimate of 1,250 molds, there would be some 5,000 cavities in current use in helmet molds.

The PHMA estimates that the top four manufacturers of bicycle helmets account for about 700 molds (or some 2,800 cavities) used in helmet production. The other 26 firms account for the remainder or, on average, 21 molds per firm (85 cavities). The PHMA estimates that 10 percent or less of the existing cavities would require redesign as a result of the proposed standard. Thus, smaller firms may need to redesign an average of 8.5 cavities. Each cavity costs approximately \$2,500, according to the trade association. On average, the one-time cost of cavity redesign for the smaller 26 firms would be about \$21,000.

The top four firms account for an estimated 75 percent of the 9 million helmets sold annually, according to PHMA. The remaining firms thus account for 25 percent, or 2.25 million helmets annually. If sales are allocated uniformly, each of the 26 firms would account for about 87,000 units. If spread over a single year's production, the average cavity redesign cost would be about 24 cents per unit.

It also should be noted that the industry routinely replaces molds (and thus, cavities), either because of style changes in helmet designs or because they wear out. The above estimates, however, assume that none would have been replaced absent the standard. Because the standard will not become effective until one year after the final rule is published, it is likely that **some** of the obsolete cavities would otherwise have been replaced by cavities that will produce complying helmets in that interim. Consequently, the estimated one-time costs associated with the replacement of mold cavities that would be attributed solely to the standard is likely to be significantly less than \$21,000.

In summary, the helmet standard may result in modest one-time costs to a few small manufacturers.

## Conclusion

In light of the relatively low per-unit costs of modifying production molds, the Commission could conclude that the rule will not have a significant impact on a substantial number of small entities.

## ENVIRONMENTAL IMPACT

The rule is not expected to affect preexisting packaging or materials of construction now used by manufacturers. Existing inventories of finished products would not be rendered unusable since Section 9(g)(1) of the CPSA provides that standards apply only to products manufactured after the effective date. . Changes in coverage areas for helmets may require modification or replacement of existing injection molds. Industry experts estimate that there are some 1,000 to 1,500 molds in current use by bicycle helmet producers, of which perhaps 10 percent are likely to be affected by the proposed standard. Molds are constructed of aluminum, commonly weighing 40-50 pounds each. Molds are also routinely replaced due to wear or to changes in style. Helmet manufacturers send these older molds back to the firm making replacements, and the older units are melted down for use in the replacement molds. Thus, the quantity of discards resulting from the rule is likely to be small. Also, it is unlikely that significant stocks of current -labels would require disposal.

The requirements of the standard are not expected to have a significant effect on the materials used in production or packaging, or in the amount of materials discarded due to the regulation. Therefore, no significant environmental effects are expected to result from the proposed rule.

**L**

**DRAFT** - 12/23/97

Harleigh Ewell - Ext. 2217  
bikhelfr.fin

Billing Code 6355-01

**CONSUMER PRODUCT SAFETY COMMISSION**

**16 CFR Part 1203**

**Final Rule: Safety Standard for Bicycle Helmets**

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Final rule.

**SUMMARY:** Pursuant to the Children's Bicycle Helmet Safety Act of 1994, the Commission is issuing a safety standard that will require all bicycle helmets to meet impact-attenuation and other requirements.

The standard establishes requirements derived from one or more of the voluntary standards applicable to bicycle helmets. In addition, the standard includes requirements specifically applicable to children's helmets and requirements to prevent helmets from coming off during an accident. The standard also contains testing and recordkeeping requirements to ensure that bicycle helmets meet the standard's requirements.

**DATES:** The standard will become effective [insert date that is 1 year after publication], as to bicycle helmets manufactured after that date. Interim mandatory standards that went into effect on March 17, 1995, will continue to apply to bicycle helmets manufactured between that date and [insert date that is 1 year after publication], inclusive.

In addition, the final standard is being designated an interim standard, so that firms will have the option of marketing helmets meeting CPSC's final standard before its effective date. This designation is effective [insert date of publication].

**FOR FURTHER INFORMATION CONTACT:** Frank Krivda, Office of Compliance, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301)504-0400 ext. 1372.

**SUPPLEMENTARY INFORMATION:**

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**Part 1203-SAFETY STANDARD FOR BICYCLE HELMETS**

**A. Introduction and Background**

1. *Introduction.* In this notice, the United States Consumer Product Safety Commission ("Commission" or "CPSC") issues a mandatory safety standard for bicycle helmets.

2. *Injury and death data.* Data from the National Center for Health Statistics ("NCHS") indicated that in 1993 there were 907 pedalcyclist (primarily bicycle-related) deaths in the United States. Of these, 17 (about 2%) were of children under the age of 5 years. Research has shown that approximately 60% of all bicycle-related deaths involved head injury. For children under age 5, about 64% involved

head injury? Information on the impact forces involved in these fatal incidents was not available, although about 90% of the pedalcyclist deaths, including those of children under age 5, involved collisions with motor vehicles.

Based on data from CPSC's National Electronic Injury Surveillance System ("NEISS"), there were an estimated 566,400 bicycle-related injuries treated in U.S. hospital emergency rooms in 1996. Of these, approximately 30% involved the head and face. A higher proportion of head injuries and facial injuries occurred to young children than to older victims.

CPSC's NEISS data showed that the types of injuries to young children were somewhat different from those to older children and adults. Younger children had a smaller proportion of concussions and internal injuries to the head than did older victims, as well as a larger proportion of relatively minor head injuries (*i.e.*, lacerations, contusions, and abrasions). The extent to which these differences can be attributed to the use of helmets, other aspects of the hazard scenario, or the physiology of young children, is not known. It is also possible that caregivers

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'Sacks, Jeffrey, J., MPH; Holmgreen, Patricia, MS; Smith Suzanne M., MD; Sosin, Daniel M., MD. "Bicycle-Associated Head Injuries and Deaths in the United States from 1984 through 1988," *Journal of the American Medical Association* 266 (December 1991): 3016-3018. Sosin, Daniel M MD, MPH; Sacks, (Jeffrey J, MD, MPH; and Webb, Kevin W "Pediatric Head Injuries and Deaths from Bicycling in the United States," *Pediatrics* 98 (November 1996): 868-870.

are more likely to bring young children to the emergency room for relatively minor injuries.

A 1993 Commission staff study of bicycle hazards indicated that when other factors were held constant statistically, the injury risk for children under age 15 was over five times the risk for older riders.<sup>2</sup> This study also indicated that children were at particular risk of head injury. About one-half of the injuries to children under age 10 involved the head, compared to one-fifth of the injuries to older riders. This may have been in part because children were significantly less likely to have been wearing a helmet than were older victims (5% of victims younger than 15 were wearing a helmet, compared to 30% of those 15 and older). However, detailed information relating the type of helmet, age of user, and other aspects of the hazard scenario to head injury severity was not available from that study. A Commission study on bicycle and helmet usage patterns found that in 1993 about 18% of bicyclists wore helmets.<sup>3</sup>

A 1996 study of about 3,400 injured bicyclists in the Seattle, Washington, area included an evaluation of the

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<sup>2</sup>Tinsworth, Deborah K., MS; Polen, Curtis; and Cassidy, Suzanne. "Bicycle-Related Injuries: Injury, Hazard, and Risk Patterns/ *International Journal for Consumer Safety* I (December 1994): 207-220.

<sup>3</sup>Rogers, Gregory B. "The Characteristics and Use Patterns of Bicycle Riders in the United States," *Journal of Safety Research* 25 (1994): 83-96.

protective effectiveness of helmets in different age groups.<sup>4</sup> When bicyclists treated in hospital emergency rooms for head injuries were compared to bicyclists who sought care for other types of injuries at the same emergency rooms, helmet use was associated with a reduction in the risk of any head injury by 69%, brain injury by 65%, and severe brain injury by 74%.

By age group, this study showed that the reduction in the risk of head injury ranged from 73% for children under 6 years to 59% for teens in the 13-19 year-old age group.<sup>5</sup> Based on the results of their study, the authors concluded that helmets were effective for all bicyclists, regardless of age, and that there was no evidence that children younger than 6 years need a different type of helmet. However, for children younger than 6 years, there was only one helmeted child with a brain injury (a concussion), and no helmeted children with severe brain injuries. Thus, the protective effects of helmets on brain injuries and severe brain injuries were not calculated for this age group.

A widely-cited 1989 study, published by the same authors, found that riders with helmets had an 85% reduction in their risk of head injury, and an 88% reduction in their

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<sup>4</sup>Thompson, Diane C., MS; Rivara, Frederick P, MD, MPH; and Thompson, Robert S., MD. "Effectiveness of Bicycle Safety Helmets in Preventing Head Injuries," *Journal of the American Medical Association* 276 (December 1996): 1968-1973.

<sup>5</sup>The estimated reduction in risk for children 6-12 years of age was 70%.

risk of brain injury, when compared to cyclists without helmets? These results were found when patients who sought emergency room care for bicycle-related head injuries were compared to bicyclists in the community who had crashes, regardless of injury or medical care. A recent study indicated that helmets may protect more against head injuries than against some facial injuries.<sup>7</sup>

3. *The Children's Bicycle Helmet Safety Act of 1994.* On June 16, 1994, the Children's Bicycle Helmet Safety Act of 1994 (the "Act" or "the Bicycle Helmet Safety Act") became law. 15 U.S.C. 6001-6006. The Act provides that bicycle helmets manufactured after March 16, 1995, conform to at least one of the following interim safety standards: (1) the American National Standards Institute (ANSI) standard designated as 290.44984, (2) the Snell Memorial Foundation standard designated as B-90, (3) the ASTM (formerly the American Society for Testing and Materials) standard designated as F 1447, or (4) any other standard that the Commission determines is appropriate. 15 U.S.C. 6004(a)-(b).

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<sup>6</sup>Thompson, Robert S., MD; Rivara, Frederick P., MD, MPH; and Thompson, Diane C., MS. "A Case Control Study of the Effectiveness of Bicycle Safety Helmets," *The New England Journal of Medicine* 320 (May 1989): 1361-1367.

<sup>7</sup>Recent research indicated that helmets reduced the risk of serious injury to the upper and middle face by about 65%, but had no significant effect on serious injury to the lower face. Thompson, Diane C., MS; Nunn, Martha E., DDS; Thompson, Robert S., MD; and Rivara, Frederick P., MD, MPH. "Effectiveness of Bicycle Safety Helmets in Preventing Serious Facial Injury." *Journal of the American Medical Association* 276 (December 1996): 1974-1975.

On March 23, 1995, the Commission published its determination that five additional voluntary safety standards for bicycle helmets are appropriate as interim mandatory standards. 60 FR 15,231. These standards are ASTM F 1447-1994; Snell B-90S, N-94, and B-95; and the Canadian voluntary standard CAN/CSA-D113.2-M89. In that notice, the Commission also clarified that the ASTM standard F 1447 referred to in the Act is the 1993 version of that standard. The interim standards are codified at 16 CFR 1203.

The Act directed the Consumer Product Safety Commission to begin a proceeding under the Administrative Procedure Act, 5 U.S.C. 553, to:

- a. review the requirements of the interim standards described above and establish a final standard based on such requirements;
- b. include in the final standard a provision to protect against the risk of helmets coming off the heads of bicycle riders;
- c. include in the final standard provisions that address the risk of injury to children; and
- d. include additional provisions as appropriate.

15 U.S.C. 6004(c).

The Act provides that the final standard shall take effect 1 year from the date it is issued. 15 U.S.C. 6004(c). The Act further provides that the final standard shall be considered to be a consumer product safety standard issued

under the CPSA. Section 9(g) (1) of the CPSA provides that a "consumer product safety standard shall be applicable only to consumer products manufactured after the effective date." Thus, the final standard, which the Commission is issuing in this notice, will become effective [insert date that is 1 year after publication], as to products manufactured after that date. The Act also provides that failure to conform to an interim standard shall be considered a violation of a consumer product safety standard issued under the Consumer Product Safety Act ("CPSA"), 15 U.S.C. 2051-2084.

The Act states that the CPSA's provisions regarding rulemaking procedures, statutory findings, and judicial review (15 U.S.C. 2056, 2058, 2060, and 2079(d)) shall not apply to the final standard or its rulemaking proceeding. 15 U.S.C. 6004(c).

The final rule is codified at 16 CFR 1203 and will replace the interim standards as to bicycle helmets manufactured on or after [insert date that is 1 year plus 1 day after publication]. 15 U.S.C. 6004(d). In addition, the final standard is also being designated an interim standard, so that firms will have the option of marketing helmets meeting CPSC's final standard before its effective date. Because providing this additional interim standard is a substantive rule that grants an exemption or relieves a restriction, the 30-day delay of an effective date otherwise



required by 5 U.S.C. 553 (d) is inapplicable, and this designation is effective [insert date of publication].

4. *The current rulemaking proceeding.* The Commission reviewed the bicycle helmet standards identified in the Act (ANSI, ASTM, and Snell), as well as international bicycle helmet standards and draft revisions of the ANSI, ASTM, and Snell standards that were then under consideration. Based on this review, the Commission developed a proposed safety standard for bicycle helmets. 59 FR 41,719 (August 15, 1994).

The Commission received 37 comments on that proposed bicycle helmet standard from 30 individuals and organizations. After considering these comments and other available information, the Commission proposed certain revisions to the originally proposed standard. 60 FR 62662 (December 6, 1995).

In response to the second proposal, the Commission received 31 comments. These comments, and additional data that have been received by the Commission since the second proposal, are discussed in Sections C-E of this notice.

#### **B. Overall Description of the Standard**

The major features of the standard issued in this notice are described below:

1. *Impact attenuation.* The standard establishes a performance test to ensure that helmets will adequately protect the head in a collision. This test involves securing

the helmet on a headform and dropping the helmet/headform assembly to achieve specified velocities so that the helmet impacts a fixed steel anvil. The helmet must provide protection at all points above a line on the helmet that has a specified relation to the headform.

Under the standard, the helmet is tested with three types of anvils (flat, hemispherical, and "curbstone," as shown in Figures 11, 12, and 13 of the standard). These anvils represent shapes of surfaces that may be encountered in actual riding conditions. Instrumentation within the headform records the headform's impact in multiples of the acceleration due to gravity ("g"). Impact tests are performed on different helmets, each of which has been subjected to one of four environmental conditions. These environments are: ambient (room temperature), high temperature (117-127°F), low temperature (1-9°F), and immersion in water for 4-24 hours.

Impacts are specified on a flat anvil from a height of 2 meters and on hemispherical and curbstone anvils from a height of 1.2 meters. Consistent with the requirements of the ANSI, Snell, and ASTM standards, the peak headform acceleration of any impact shall not exceed 300 g for an adult helmet, the value originally proposed for both adult and child helmets. In the revised proposed standard, the acceptable g value for children's helmets was reduced to 250 g and a lower headform drop mass than that for adults was

specified (3.90 kg). As explained in section C of this notice, however, the final rule specifies that the 5-kg headform mass and the 300-g peak acceleration criterion will apply to all helmets subject to the standard, as specified in the original proposal.

The standard provides that a helmet fails the performance test if a failure can be induced under any combination of impact site, anvil type, anvil impact order, or conditioning environment permissible under the standard. Thus, the Commission will test for a "worst case" combination of test parameters. What constitutes a worst case may vary, depending on the particular helmet involved.

2. *Children's helmets: head coverage.* The standard specifies that helmets for small children (under age 5) must cover a larger portion of the head than must helmets for older persons. A study by Biokinetics & Associates Ltd. found differences in anthropometric characteristics between young children's heads and older children's and adult's heads.'

3. *Retention system.* The standard requires that helmets be able to meet a test of the dynamic strength of the retention system. This test ensures that the chin strap is strong enough to prevent breakage or excessive elongation of

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<sup>8</sup>Heh, S., Log of ASTM F08.53 Headgear Subcommittee meeting held May 21, 1992, date of entry June 17, 1992. Office of the Secretary, U.S. Consumer Product Safety Commission, Washington, DC 20207.

the strap that could allow a helmet to come off during an accident.

The test requires that the chin strap remain intact and not elongate more than 30 mm (1.2 in) when subjected to a "shock load" of a 4-kg (8.8-lb) weight falling a distance of 0.6 m (2 ft) onto a steel stop anvil (see Figure 8). This test is performed on one helmet under ambient conditions and on three other helmets after each is subjected to one of the different hot, cold, and wet environments.

4. *Peripheral vision.* Section 1203.14 of the standard requires that a helmet shall allow a field of vision of 105 degrees to both the left and right of straight ahead. This requirement is consistent with the ANSI, ASTM, and Snell standards.

5. *Labels and instructions.* Section 1203.6 of the standard requires certain labels on the helmet. These labels provide the model designation and warnings regarding the protective limitations of the helmet. The labels also provide instructions regarding how to care for the helmet and what to do if the helmet receives an impact. The labels also must carry a warning that for maximum protection the helmet must be fitted and attached properly to the wearer's head in accordance with the manufacturer's fitting instructions.

The standard also requires that helmets be accompanied by fitting and positioning instructions, including a graphic

representation of proper positioning. As noted above, the standard has performance criteria for the effectiveness of the retention system in keeping a helmet on the wearer's head. However, these criteria may not be effective if the helmet is not well matched to the wearer's head and carefully adjusted to obtain the best fit.

To avoid damaging the helmet by contacting it with harmful common substances, the helmet must be labeled with any recommended cleaning agents, a list of any known common substances that will cause damage, and instructions to avoid contact between such substances and the helmet.

6. *Positional stability (roll off)*. The standard specifies a test procedure and requirement for the retention system's effectiveness in preventing a helmet from "rolling off" a head. The procedure specifies a dynamic impact load of a 4-kg (8.8-lb) weight dropped from a height of 0.6 m (2 ft) to impact a steel stop anvil. This load is applied to the edge of a helmet that is placed on a headform on a support stand (see Figure 7). The helmet fails if it comes off the headform during the test.

The safety requirements discussed in paragraphs (1)-(6) above are issued pursuant to the Bicycle Helmet Safety Act and are codified as Subpart A of the Safety Standard for Bicycle Helmets.

7. *Certification labels and testing program*. Under the authority of section 14(a) of the CPSA, the Commission is

also issuing certification testing and labeling requirements to ensure that bicycle helmets meet the standard's safety requirements. These certification requirements are in Subpart B of the Safety Standard for Bicycle Helmets and are discussed in section D of this notice.

8. *Recordkeeping.* Under the authority of section 16(b) of the CPSA, the Commission is issuing requirements that manufacturers (including importers) maintain records of the required certification testing. These recordkeeping requirements are found in Subpart C of the Safety Standard for Bicycle Helmets and are discussed in section E of this notice.

9. *Interim standards.* The interim standards, which are currently codified as 16 CFR 1203, will continue to apply to bicycle helmets manufactured from March 16, 1995, to [insert date that is 1 year after publication]. Accordingly, the interim standards will continue to be codified, as Subpart D of the standard. Also, Subparts A-C of the standard are being added as an interim standard, so that firms will have the option of marketing helmets meeting CPSC's final standard before its effective date.

### **C. The Final Standard-Comments, Responses, and Other Changes**

This section discusses comments on the second proposal, as well as other issues that were dealt with in deciding the requirements of the final rule. Numbers in brackets refer to

the number assigned by the Commission's Office of the Secretary to a comment on the second proposal.

1. *Accident scenarios.* Mr. Frank Sabatano [14], President of the London Bridge BMX Association, recommended that bike helmets be constructed so as to accommodate more serious accidents that might result from a child bicycle racing or jumping rather than merely riding on a path or street.

While no helmet can protect against every conceivable impact, the available evidence supports the conclusion that helmets designed to meet the CPSC standard will be very effective in protecting against serious injury within a wide range of common bicycle riding conditions. This would include many of the impact conditions that could occur during racing or jumping. Furthermore, a standard for all bicycle helmets has to balance the benefits of more protective helmets against the additional cost, weight, bulk, and discomfort that more protection may impose. Such undesirable qualities may discourage many users from wearing helmets designed to protect against very severe impacts, which could more than cancel the effects of the additional protective qualities. Thus, the force with which the helmets are impacted in the standard's performance test has not been increased.

2. *Future revisions.* Randy Swart, Director of the Bicycle Helmet Safety Institute [16], suggested that the

following items be considered as future revisions to the CPSC standard as progress in head protection research continues:

- a. A test that requires the retention system to be easily adjusted for good fit.
- b. A test for protection against rotational injury.
- c. A test to limit localized loads or "point loading."
- d. A test for damage to the helmet by hair oil or other common consumer preparations.
- e. A test of the retention system after impact to simulate field conditions.
- f. A test to ensure that visors and mirrors are shatter-resistant and easily peel off in a crash.

The Commission agrees that it is important to periodically review research related to improvements in head protection to determine if revisions should be considered for the CPSC bicycle helmet standard.

3. *Compliance with third-party standards as compliance with the rule.* Jane McCormack [7] requested that the Commission ensure that bike helmets meet the Snell requirements. Norte Vista Medical Center [15] requested that helmets certified to the Snell B-95 or Snell N-94 standards be considered to be in compliance with the mandatory standard.

The Commission declines to make these changes. One of the objectives of the Bicycle Helmet Safety Act is to



establish a unified bicycle helmet standard that is recognized nationally by all manufacturers and consumers. It would defeat Congress' intent to add language to the regulation stating **that** certified conformance to any existing voluntary standard satisfies compliance with the mandatory rule.

4. *Scope of the standard.*

a. *Definition of "bicycle helmet ."* The original proposal defined bicycle helmet as "any headgear marketed as suitable for providing protection from head injuries while riding a bicycle." The definition of bicycle helmet in the second proposal included not only products specifically marketed for use as a bicycle helmet but also those products that can be reasonably foreseen to be used for that purpose.

Bell Sports [12] suggested that the definition of bicycle helmet should not include all products with a reasonably foreseeable use as a device intended to provide protection from head injuries while riding a bicycle. Bell maintains there are many helmets that have a foreseeable use by bike riders that should not have to be certified to a bike helmet standard (e.g., baseball and roller hockey helmets).

The respondent suggested that football helmets, baseball batting helmets, and motorcycle helmets will also have "easily foreseeable" uses as bicycle helmets.

The Commission did not intend for the definition of bicycle helmet to include football helmets, baseball batting helmets, and motorcycle helmets that are not marketed for use while bicycling. It seems unlikely that a helmet that is not marketed or promoted for bicycle use will have a reasonably foreseeable use as a bicycle helmet. Thus, the "reasonably foreseeable,, language is unnecessary. Therefore, in order for the definition to provide more guidance, the "reasonably foreseeable,, language has been deleted, and the definition of bicycle helmet has been changed to read:

"Bicycle helmet means any headgear that either is specifically marketed as, or implied through marketing or promotion to be, a device intended to provide protection from head injuries while riding a bicycle.,,

Helmets specifically marketed for exclusive use in a designated activity such as skateboarding, rollerblading, baseball, roller hockey, etc., would be excluded from this definition because the specific focus of their marketing makes it unlikely that such helmets would be purchased for other than their stated use. However, a multi-purpose helmet---one marketed or represented as providing protection either during **general** use or in a variety of specific activities other than bicycling---would fall within the definition of bicycle helmet if a reasonable consumer could conclude, based on the helmet's marketing or

representations, that bicycling is among the activities in which the helmet is intended to be used.

In making this determination, the Commission will consider the types of specific activities, if any, for which the helmet is marketed, the similarity of the appearance, design, and construction of the helmet to other helmets marketed or recognized as bicycle helmets, and the presence, prominence, and clarity of any warnings, on the helmet or its packaging or promotional materials, against the use of the helmet as a bicycle helmet. The presence of warnings or disclaimers advising against the use of a multi-purpose helmet during bicycling is a relevant, but not necessarily controlling, factor in the determination of whether a multi-purpose helmet is a bicycle helmet. A multi-purpose helmet marketed without specific reference to the activities in which the helmet is to be used will be presumed to be a bicycle helmet.

b. *Multiple-activity helmets.* Some commenters on the original proposal recommended that the CPSC include provisions for children's bicycle helmets to provide protection in activities in addition to bicycling, such as skateboarding, skating, sledding, and the like. Two commenters recommended that the CPSC bike helmet standard also apply to helmets marketed for roller skating and in-line skating. Other comments stated that the Commission

should not delay promulgation of the bike helmet standard while multi-activity issues are explored.

The Commission did not propose that the standard address activities other than bicycling, because the CPSC's authority under the Bicycle Helmet Safety Act is to set mandatory requirements for **bicycle** helmets. Establishing criteria for products other than bicycle helmets would require the Commission to follow the procedures and make the findings prescribed by the CPSA or the Federal Hazardous Substances Act ("FHSA").

The National Safe Kids Campaign ("NSKC") [22] and the Consumer Federation of America ("CFA") [23] recognized that the scope of the CPSC standard must be for bicycle helmets, but requested the Commission to move forward in investigating the issues related to multi-activity helmets. In a comment on the revised proposal, Mr. Frank Sabatano, President of the London Bridge BMX Association [14], recommended that bicycle helmets should serve as multi-purpose protective devices for various sports such as bicycle riding, bicycle racing, skateboarding, and in-line skating.

The Commission intends to monitor developments relevant to the multi-activity issue. Wheeled recreational activities such as traditional roller skating and in-line skating are typically conducted on the same surfaces as bicycling, and can generate speeds similar to bicycling. Therefore, it is

reasonable to assume that helmets that meet the requirements in the CPSC bike helmet standard will also provide head protection for roller/in-line skating and perhaps some other recreational activities. However, as discussed in the December 6, **1995 Federal Register** notice on the proposed rule, the Commission does not have sufficient data on the benefits and costs of additional features directed at injuries incurred in activities other than bicycling to make the statutory findings that would be needed to issue a requirement for such features under either the CPSA or FHSA. Also, procedures in addition to those required by the Bicycle Helmet Safety Act would have to be followed. The Commission does not want to delay establishment of a mandatory bicycle helmet standard in order to pursue rulemaking for other types of helmets. Accordingly, the final standard only addresses requirements for bicycle helmets. However, as discussed below, the Commission will examine what actions it could take to encourage the use of bicycle helmets in activities that present head injury risks similar to those in bicycling.

NSKC [22] also urged the CPSC to work with community-based organizations to develop a comprehensive educational campaign regarding the importance of wearing a federally-approved bicycle helmet when participating in non-motorized activities other than bicycling. The Commission will

consider what activities are appropriate in this regard when setting its priorities for future activities.

5. *Projections.* Projections on the inner or outer surface of a helmet can concentrate applied forces and cause injuries. Therefore, the revised proposed standard provided that projections on the outer surface would not exceed 7 mm (0.28 in) unless they break away or collapse on impact and that projections on the helmet's interior not make contact with the headform during testing.

NSKC [22] urged that the Commission prohibit any external projections on helmets intended for children. NSKC believes that external projections, such as visors, are unnecessary components of helmets intended for children.

With regard to a possible hazard from external projections on children's helmets, § 1203.7 of the standard requires that helmets must pass all tests, both with and without any attachments that may be offered by the manufacturer. This provision, and the requirement that any external projections shall break away or collapse, will address the potential hazard of external projections on helmets intended for riders of all ages. The proposed language is consistent with existing voluntary standards, and no changes were made in response to this comment.

SwRI [2] remarked that the proposed standard does not state how to determine if an internal projection makes contact with the headform during testing. NSKC [22] also

suggested that instead of requiring inner surface projections to not exceed 2 mm, the inside of the helmet should contain no sharp edges or rigid internal projections.

After considering these comments, the Commission decided to revise the section on internal projections to eliminate the requirement that internal projections not make contact with the headform during testing, while retaining the requirement that such projection not exceed 2 mm (0.08 in). The purpose of this section is to prohibit potentially hazardous projections but make some allowance for common helmet construction practices. The language above is consistent with Snell helmet standards, and the Commission is not aware of safety problems associated with projections on helmets meeting existing standards.

6. *Requirements for qualities of fitting pads.* NSKC [22] urged the Commission to include safety requirements for fitting pads in the final standard. The commenter asserted that since fitting pads are often necessary to ensure a secure fit, the standard should address the integrity of the materials used to construct them, as well as their thickness, durability, and adhesiveness.

CPSC staff has no information that long-term integrity of fitting pads is a problem with helmets meeting existing standards. The interim mandatory standards have no provisions of the type suggested by the commenter. Introducing new requirements for fitting pads is not

essential at this time, and no change to the proposed standard has been made in response to this comment.

7. *Impact attenuation criteria.*

a. *Extent of protection.* The originally proposed CPSC standard, and current U.S. voluntary bicycle helmet standards, specified an extent-of-protection boundary and an impact test line. The extent-of-protection boundary defines the area of the head that must be covered by the helmet. The impact test line designates the lowest point on the helmet where the center of an anvil may be aligned for testing. The second proposal specified a single impact test line and no extent-of-protection boundary requirement. Not requiring specific helmet coverage allows manufacturers the flexibility to include desirable features, such as a central rear vent, provided the features do not hinder the helmet's ability to meet the impact requirements if tested anywhere on or above the impact test line. Accordingly, the Commission deleted the extent-of-protection boundary from the revised proposed standard.

In commenting on the latter proposal, Snell [28] discussed the practical problems in certifying helmets when only an impact test line is specified. Snell recommended that the standard be amended to require coverage below the impact test line, particularly at the front and rear of a helmet.



The Commission disagrees with this comment. Coverage does not imply impact protection. The only area on the helmet required to pass impact protection requirements is the area above the impact test line. Therefore, it is unnecessary to specify additional coverage below the test line.

The manufacturers of the Protective Headgear Manufacturing Association ("PHMA") [29] reported that they believed the proposed CPSC standard requires coverage at the rear of the head lower than any other standard. They stated that they are not aware of any studies indicating that lower coverage at the rear is warranted. They also stated their concern that the helmet-wearing public will not purchase helmets that are perceived to be more "clunky" or "bulbous," and that helmets with extended coverage are likely to be so perceived. Mr. Becker of Snell [28] stated that the CPSC-proposed coverages are more extensive than any current U.S. standard, except for Snell's B-95 and N-94 helmet standards. He stated that unless the CPSC coverage is changed, many contemporary helmet models that have protected their wearers from life-threatening injury will disappear from the market. Snell urged that the CPSC adopt the coverage described in the ASTM F1447-94 or Snell B-90 standards. According to this commenter, these coverages reflect the current state of the industry and should be expected of every bicycle helmet.

The proposed CPSC impact test line is not lower at the rear of the helmet than all other standards. The proposed CPSC impact test line is somewhat lower at the rear of the helmet than the impact test lines in the Snell B-90 and ASTM F1447 standards. However, the CPSC line is higher at the rear of the helmet than the impact test lines in the following interim mandatory standards: Snell B-95 and N-94, CAN/CSA-D113.2, and ANSI Z90.4-1984.

CPSC is aware of two studies that show that it is not uncommon for helmets involved in accidents to suffer impacts at the rear portion of the helmet. A Bell Sports study of 1100 helmets involved in accidents found that 26% of the impacts were at the rear of the helmet and that the majority of these rear impacts occurred within 50 mm of the bottom edge of the helmet.<sup>9</sup> Another study, by Technisearch of Australia, examined the effect of lowering the impact test line from the Snell B-90 standard to the impact test lines in the Snell B-95 and N-94 standards? The Technisearch study was based on examinations of 104 bicycle helmets whose wearers sustained impacts to the head during accidents. The study concluded that the B-90 standard test line would have provided coverage for 51% of the impacts. The impact test

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<sup>9</sup>Dean Fisher and Terry Stern, "Helmets Work!," Bell Sports, Inc., AAAM/IRCOBI Conference, Lyon, France (September 1994).

"Martin Williams, "Test Line Requirements and Snell B-95 and N-94 Standards," Technisearch Engineering & Scientific Services (August 1994).

line of the B-95 standard would provide coverage for 65% of the impacts. The increase from 51% to 65% was represented by 20 additional impact sites that would fall within the area of the B-95 coverage, including 8 impact sites at the rear portion of the helmet.

One of the directions of the Children's Bicycle Helmet Safety Act is to include provisions from existing appropriate standards for adoption in the final CPSC standard. The CPSC impact test line is a reasonable requirement that will improve the protective characteristics of helmets overall, while falling within test lines of established North American bicycle helmet standards.

b. *Distance between impacts.* A commenter on the original proposal recommended revising the minimum distance between impact sites from the originally proposed "one fifth the circumference of the helmet" to 120 mm. The Commission believed that 120 mm allows sufficient distance to minimize the effects of impact site proximity and provides a more straightforward measurement than the original one-fifth circumference criteria. Accordingly, the Commission adopted this recommendation in the revised proposal.

Two commenters on the revised proposal [27 and 29] recommended a minimum distance between impacts of 150 mm, or about 6 inches. One of these commenters stated that the CPSC made the minimum distance shorter than those in voluntary standards.

The Commission selected the 120-mm impact spacing based on recently balloted ASTM headgear standards. The Snell B-95 standard also specifies a minimum impact separation of 120 mm. This distance is consistent with the Snell B-90 specification of 1/6th the maximum helmet circumference, if calculated for smaller helmets. A minimum impact spacing of 150 mm would limit flexibility in choosing impact sites, especially on smaller helmets. Therefore, no change to the proposed rule was made in response to this comment.

c. *Impact velocity tolerance.* The University of Southern California's Head Protection Research Lab ("USC-HPRL") [8] suggested that the tolerance for the impact velocity be changed from  $\pm 3\%$  to  $-0\%$  to  $+5\%$  to ensure that impact testing is done at no less than the specified velocity.

The difference between tolerances of  $\pm 3\%$  and  $-0\%$ ,  $+5\%$  has little practical significance for a 300-g criterion. Since the commenter's suggestion would not produce a significant safety benefit, the Commission made no change to the proposed rule in this regard.

d. *Other requirements for Children's helmets: peak-g value and drop mass.* One of the provisions of The Children's Bicycle Helmet Safety Act of 1994 is that the Commission include in the final CPSC standard provisions that address the risk of injury to children. This does not require that children's helmets be subject to requirements that differ

from those for adults, helmets; it requires only that the final standard be appropriate for children's helmets. The issue of whether special standard provisions for young children's helmets are needed has been debated for several years by head protection experts.

A young child's skull has different mechanical properties than the skull of an older child or adult. These differences are especially evident for children under the age of 5 years. Their skulls have a lower degree of calcification, making them more flexible than adult skulls. During an impact to the head, the increased skull flexibility results in a greater transfer of kinetic energy from the impact site to the brain tissue. Besides the different mechanical properties, the mass of a young child's head is also different from that of a more mature person's head. Studies show that the head mass of children under the age of 5 years ranges from approximately 2.8 to 3.9 kg. This mass is lower than the 5-kg test headform mass specified in current U.S. bicycle helmet standards.

The Commission first proposed a safety standard for bicycle helmets on August 15, 1994. In that proposal, the only special provision for helmets for children under 5 years was an increased area of head coverage. On December 6, 1995, however, the Commission proposed special provisions for headform mass, peak-g limit, and head coverage for bicycle helmets for children under 5 years. The special

children's provisions: were based on the ongoing work of voluntary standards organizations and proposals at that time in the technical literature. The following comparison shows the CPSC-proposed test parameters for helmets for children under 5 years and for helmets for older persons.

	<u>Under 5</u>	<u>5 and older</u>
Mass of test headform	3.9 kg	5.0 kg
Peak-g limit	250-g	300-g
Head Coverage	more coverage at rear and sides of head	

The proposal for increased head coverage of children's helmets is relatively uncontroversial, and the final rule contains this requirement. However, the Commission has reassessed the proposed headform mass and peak-g requirements. The Commission's conclusions are discussed in detail below.

A few respondents to the proposed rule [8,16] supported the lower mass and lower peak-g provisions, believing that they will lead to an improvement in head protection for small children. One of these respondents, however, urged the Commission to consider the most recent research on this

subject before including the special provisions in a final standard. One respondent [12] favored a reduced headform mass provision, but did not recommend a reduced peak-g provision, stating that it could result in a helmet with a lower margin of safety.

Several respondents [3, 4, 6, 9, 10, 13, 15, 18, 19, 27, 28, 29, 30] questioned whether it is advisable to move forward with the provisions of a reduced-mass headform and a lower limit for peak acceleration. Some respondents **suggested** that special children's provisions should not be **adopted** since studies show that children's helmets as they exist today provide excellent protection.

Studies by researchers at the Harborview Injury Prevention and Research Center have shown that bicycle helmets that meet existing standards are effective in protecting against serious head and brain injuries? One of the items analyzed in the most recent Harborview study was whether the protective effects of bicycle helmets vary by the age of the user. For four age groups of riders, they estimated the protective effect of helmets against three

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<sup>11</sup>Thompson, Robert S., MD; Rivara, Frederick P, MD, MPH; and Thompson, Diane C., MS "A Case Control Study of the Effectiveness of Bicycle Safety Helmets,,, *The New England Journal of Medicine* 320 [May 1989]: 1361-1367. Thompson, Diane C., MS; Rivara,, Frederick P, MD, MPH; and Thompson, Robert S., MD. "Effectiveness of Bicycle Safety Helmets in Preventing Head Injuries,,, *Journal of the American Medical Association* 276 (December 1996): 1968-1973.